CERTIFICATE OF ANALYSIS

(Certificate No. KMI017088-01)

Release Date: 21/08/2024 **Re-test Date:** 20/08/2027

N-Nitroso Ibrutinib Impurity 1

Identification

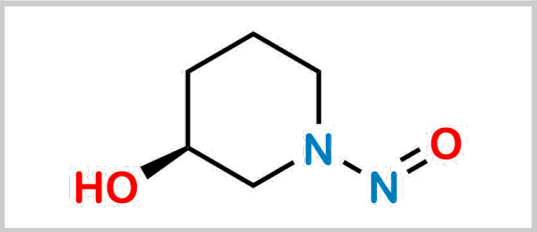
Chemical Name :
(S)-1-Nitrosopiperidin-3-ol

CAT No. : KMI017088

CAS No. : 2380680-64-6

Molecular Formula : C5H10N2O2

Molecular Weight : 130.1



Analytical Information

Batch No.	: IBR-IMP-1-NO-073-345	**Solubility**	: Methanol
Description	: Light Yellow Liquid	**Mass**	: Confirm
HPLC Purity	: 99.83 %	**IR**	: Confirm
Weight Loss By TGA	: 1.97 %	**1H NMR**	: Confirm
% Potency	: 97.86 %		

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = [100 - 1.97(Weight Loss By TGA)] x [99.83(HPLC Purity)]/100 = 97.86 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		21/08/2024
Reviewed & Approved By	Quality Control	Jatin Patel		21/08/2024

Attachments : COA, HPLC, MASS, 1HNMR, IR and TGA